REMARKS

Status of the Claims

Claims 10-14 and 21-30 are pending in this application. Claims 1-9 and 15-20 have been canceled. Claim 10 is independent. Claims 10, 11, 12 and14 are herein amended. Support for the amendments to claims 10 and 11 can be found throughout the Specification, *see* page 2, lines 7-12; page 2, lines 19-27; page 3, lines 1-6; page 3, lines 15-19; page 4, lines 1-4; and original claim 15 in the originally filed application. New claims 21-30 have been added. Support for new claims 21-30 can be found throughout the Specification, *see* page 5, lines 1-14; page 4, lines 1-16; page 5, last paragraph; page 6, lines 1-9; the Examples and original claims 2-8 in the originally filed application. No new matter is added by way of these amendments. Reconsideration of this application is respectfully requested.

Priority under 35 U.S.C. § 119

Applicants thank the Examiner for acknowledging Applicants' claim for foreign priority under 35 U.S.C. § 119, and receipt of the certified priority document.

Information Disclosure Citation

Applicants thank the Examiner for considering the references supplied with the Information Disclosure Statement filed on 01/12/2007 and 03/14/2008, and for providing Applicants with an initialed copy of the PTO-SB08 form filed therewith.

Rejection under 35 U.S.C. § 101

Claim 19 stands rejected under 35 U.S.C. § 101.

While not conceding the appropriateness of the Examiner's rejection, but merely to advance prosecution of the instant application, Applicants respectfully submit that claim 19 has been canceled, thus rendering this rejection under 35 U.S.C. § 101 moot. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection under 35 U.S.C. § 112, 2nd Paragraph

Claims 10 and 12-14 stand rejected under 35 U.S.C. § 112, 2nd Paragraph. The Examiner asserts that the steps of the claimed immunoassay of claims 10 and 12-14 are not clearly defined.

In order to overcome this rejection, Applicants have amended independent claim 10 to correct the deficiency specifically pointed out by the Examiner. Applicants respectfully submit that the claims, as amended, particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection under 35 U.S.C. § 102(a)

Claims 10-14 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Wada et al., WO 2004/092733 ("Wada"). This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

As amended, independent claim 10 recites "An immunoagglutination immunoassay for inhibiting decrease in measured values in immunoassays, comprising: mixing a test sample with an agent for inhibiting decrease in measured values in immunoagglutination immunoassays, caused by an interfering substance(s), which agent is an ionic surfactant having a molecular weight of 1000 to 100,000, said ionic surfactant being a polymer in which a hydrophobic cyclic monomer(s) having an ionic functional group(s) is(are) polymerized to form a mixture of said test sample and said agent."

Wada relates to a migration shift assay. Wada describes the step of contacting a sample with an affinity molecule to form a complex in the presence of a charged polymer. In addition, Wada discloses a method wherein a formed complex is separated after the step of contacting the sample with the affinity molecule.

However, Wada does not disclose or suggest an immunoagglutination method. In contrast, the present invention, as amended, is directed to an immunoagglutination method, which can be performed without a separation step (see claims 21, 29 and 30 which require that measured values in the reacted mixture are determined). Moreover, Applicants submit that Wada fails to describe the second step of subjecting a test sample to antigen-antibody reaction with "sensitized particles" or with an antiserum (see claim 11 and claims dependent thereon). Although Wada mentions polystyrene latex, the polystyrene latex is used only as a charged carrier molecule. Accordingly, Wada is silent regarding the immunoagglutination method. Thus, Applicants submit that Wada fails to describe all of the elements of claims 10-14.

Rejection under 35 U.S.C. § 102(b)

Claims 10-14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Moghaddam et al., US Patent 5,972,718 ("Moghaddam").

Further, claims 10-14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Senn et al., WO 91/10747 ("Senn").

Further, claims 10-13 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bloch et al., WO 90/02202 ("Bloch").

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

Moghaddam relates to a method of detecting heparin-induced antibodies to screen for heparin-induced thrombocytopenia. In this method, human platelet factor 4 is bound to a polymer carrying negative charges. Moghaddam also discloses using latex particles as a solid phase.

However, the method of Moghaddam is carried out after forming a complex of human platelet factor 4 and the polymer. Further, even when latex particles are used, the latex particles are coated with the complex.

In contrast, in the immunoassay of the present invention, the particles are coated with an antigen or antibody, and the polymer surfactant is not coated on the particles. Thus, Applicants submit that the present invention, as amended, is not anticipated by Moghaddam.

Senn discloses an immunoassay. However, Senn is totally silent about an agglutination immunoassay. Thus, Applicants submit that Senn fails to describe all of the elements of the amended claims.

Bloch discloses a method for inactivating peroxidatic catalysts in a test sample. However, Bloch is totally silent about an agglutination immunoassay. Therefore, Applicants submit that the present invention, as amended, is not anticipated by Bloch.

Rejection under 35 U.S.C. § 102(f)

Claims 1-9 stand rejected under 35 U.S.C. § 102(f).

While not conceding the appropriateness of the Examiner's rejection, but merely to advance prosecution of the instant application, Applicants respectfully submit that claims 1-9 have been canceled, thus rendering this rejection under 35 U.S.C. § 102(f) moot. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 10-14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Mutsumi et al., JP 2003-149244 ("Mutsumi") in view of Fluka Catalog, 1999/2000, pages 1115, 1132.

Mutsumi discloses an immunoassay in the presence of an alkylbenzene sulfonate anionic surfactant in order to inhibit the so called "prozone phenomenon." The prozone phenomenon is the phenomenon where a sample contains an excess amount of the antigen or antibody to be quantified by the immunoassay, and the quantified amount of the target antigen or antibody is smaller than the actual amount.

In contrast, in the present invention, the decrease in measured values in the immunoassay is caused by one or more interfering substance, and not by the prozone phenomenon. Moreover, since the prozone phenomenon occurs when the concentration of the antigen or antibody to be

quantified by the immunoassay is in excess, the sample serum used in the examples of Mutsumi is not diluted, while in the examples of the present invention, the effect of the present invention is tested using serially diluted serum samples, in most of which the prozone phenomenon does not occur.

Furthermore, as expressly stated in claim 10 of the present application, the ionic surfactant employed is a **polymer** in which a hydrophobic cyclic monomer(s) having an ionic functional group(s) is(are) **polymerized**. In contrast, Mutsumi fails to disclose or suggest the use of such a polymer.

In addition, Mutsumi lists a number of preferred anionic surfactants which may be used in the invention, *see* Mutsumi, paragraph [0012]. The anionic surfactants disclosed my Mutsumi include: sodium alkylphenylether disulfonates, **sodium alkylnapthalene sulfonates**, sodium alkane sulfonates, sodium polyoxyethylenelauryl ether sulfate esters, higher alkylether sulfate esters, sodium polyoxyethylenelauryl ether sulfate esters, **alkylbenze sulfonates** and polyoxyethylenealkylallyl sulfates (the emphasized anionic surfactants are those employed in the Experimental Report mentioned below for comparison). However, none of these anionic surfactants disclosed by Mutsumi are within the scope of "a polymer in which a hydrophobic cyclic monomer(s) having an ionic functional group(s) is(are) polymerized" as recited, *inter alia*, in claim 10 of the present application.

The cited Fluka Catalog does nothing more than to show that the polymeric anionic surfactant *per se* used in the present invention was known. However, use of the polymeric anionic surfactant in the agglutination immunoassay is not disclosed or suggested in the Fluka Catalog.

Experimental Report

The following experiments were performed in order to show the novel and nonobvious features of the present invention. We note that this Experimental Report will later be converted into a Declaration.

In the experiments, the inhibiting decrease in measured values in immunoassays was compared by an anionic surfactant of the present invention with anionic surfactants described by

Mutsumi. The anionic surfactant of the present invention, sodium polystyrene sulfonate, is described within the scope of claim 10. This anionic surfactant was compared to the anionic surfactants, sodium alkylnaphthalene sulfonate and alkylbenzene sulfonate, described by Mutsumi. The results show a much higher inhibiting decrease in measured value effect from the present invention using an anionic surfactant within the scope of claim 10, than the anionic surfactants specifically described as preferred anionic surfactants by Mutsumi. Thus, the inventive step of the present invention is clearly established from these experiments.

New Claims

Claims 21-30 have been added for the Examiner's consideration.

Applicants submit that claims 21-30 depend, either directly or indirectly, from independent claim 10, and are therefore allowable based on their dependence from claim 10 which is believed to be allowable.

In addition, claims 21-30 recite further limitations which are not disclosed or made obvious by the applied prior art references.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Shawn Hamidinia, PhD (Reg. No. 58,931) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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ATTACHMENT: EXPERIMENTAL REPORT (PAGES 1-3)

SAH
GMM/SAH/nmb

EXPERIMENTAL REPORT

1. Materials and Methods

Reagents for latex turbidimetric assay for measuring myoglobin (Mb) having the composition shown in Table 1 below were prepared.

Table 1

First Reagent	Comparative Example A	170 mM glycine buffer 50 mM EDTA 100 mM sodium chloride 0.01wt% sodium linear C_{10}-C_{16} monoalkylbenzene sulfonate*1
	Comparative Example B	170 mM glycine buffer 50 mM EDTA 100 mM sodium chloride 0.01wt% sodium alkylnaphthalene sulfonate*2
	Example C	170 mM glycine buffer 50 mM EDTA 100 mM sodium chloride 0.01wt% sodium polystyrene *p*-sulfonate
	Control	170 mM glycine buffer 50 mM EDTA 100 mM sodium chloride
Second Reagent	Mb-Latex "SEIKEN"/Latex suspension (produced by Denka Seiken)	

*1: NEWREX SOFT TYPE 30 (commercially available from NIPPON OIL & FATS)
*2: PELEX NB-L (commercially available from KAO CORPORATION)

Thus, the compositions of the reagents were exactly the same among Comparative Examples A and B and Example C except that the type of the surfactant was different.

Test Sample Randomly selected one clinical sample (serum)

Measurements

Preparation of Sample: The test sample was serially diluted in 1/10 (10-fold dilution) to 10/10 (not diluted) with physiological saline as a diluent.

Measurement Method: Measurement by Toshiba TBA-30R automatic analyzer

Measurements were performed using the respective reagents prepared described

above. To 20 μL of the sample prepared as described above, 200 μL of the first reagent was added and the mixture was stirred at 37°C. After leaving the mixture to stand for 5 minutes, 100 μL of the second reagent was added and the resulting mixture was stirred at 37°C, followed by measuring the agglutination reaction in about 2 minutes in terms of the amount of the change in absorbance at 570 nm. Samples having known concentrations had been preliminarily subjected to the measurement under the same conditions, and a calibration curve showing the relationship between the concentration and the amount of the change in absorbance had been preliminarily prepared. The measured values (ng/mL) were obtained by applying the measured absorbance to the calibration curve.

2. Results

The results are shown in Fig. 1 below.

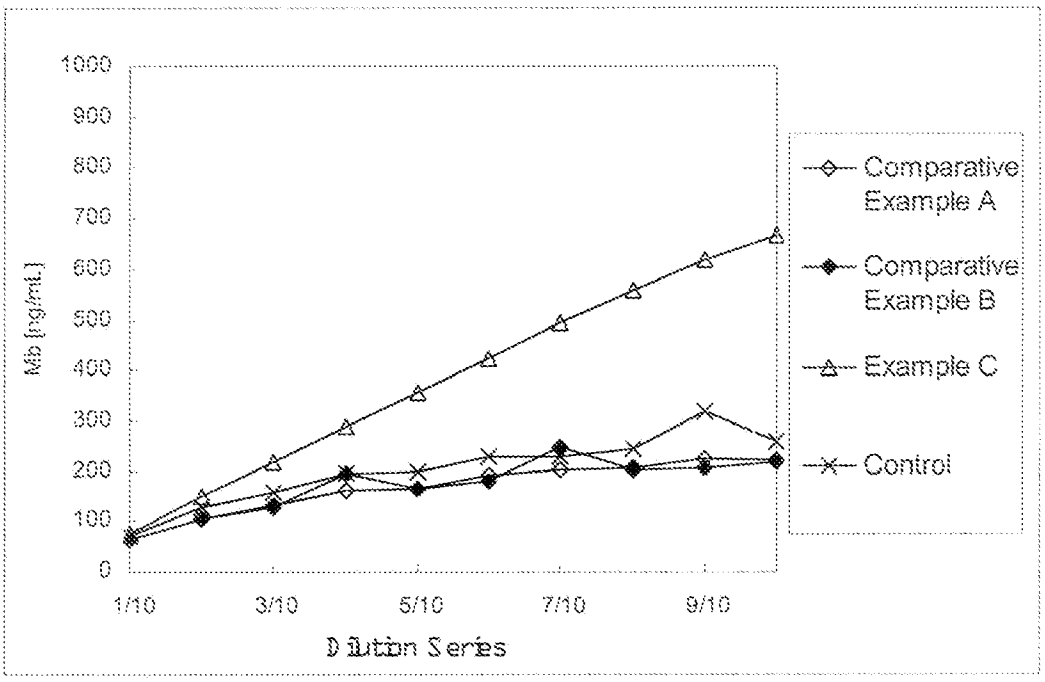

Fig. 1

As shown in Fig. 1, when the dilution was 10-fold, the measured amounts of myoglobin (Mb) were the same in any example, comparative examples and the control.

In contrast, when the sample was not diluted (10/10), Example C alone according to the present invention attained the correct measurement (i.e., the measured amount was about 10 times that when the dilution was 10-fold), while Comparative Example A and Comparative Example B using the anion surfactants specifically mentioned in D1, respectively, as well as the control using no surfactant, resulted in similar measured amounts which were much smaller than the correct amount.

Thus, it was proved that the present invention has a prominent effect to inhibit decrease in measured values in immunoassays, thereby promoting the accuracy of immunoassays. In contrast, the anionic surfactants specifically mentioned in D1 did not have such an effect because the results were substantially the same as the control wherein no surfactant was used.